CLAIMS

What is claimed is

1. A pharmaceutical composition, comprising:

a water-soluble, acid-labile drug enteric-coated with a enteric coating material that dissolves at pH above about 5.2.

2. The pharmaceutical composition of claim 1, wherein the solubility of the drug is above 1 mg/ml in water or aqueous solution.

3. The pharmaceutical composition of claim 1, wherein the solubility of the drug is above 10 mg/ml in water or aqueous solution.

4. The pharmaceutical composition of claim 1, wherein the drug is labile at pH lower than 5.0.

5. The pharmaceutical composition of claim 1, wherein the drug is labile at pH lower than 2.0.

6. The pharmaceutical composition of claim 1, wherein the drug is a cytidine analog.

7. The pharmaceutical composition of claim 6, wherein the cytidine analog is 5-azacytidine or decitabine.

8. The pharmaceutical composition of claim 1, wherein the drug is a 2'-deoxyadenosine analog.

9. The pharmaceutical composition of claim 8, wherein the 2'-deoxyadenosine analog is pentostatin, fludarabine, or 2-chloro-2'-deoxyadenosine.

10. The pharmaceutical composition of claim 1, wherein the enteric coating material is pH-sensitive and dissolves at pH above about 5.5.

11. The pharmaceutical composition of claim 1, wherein the enteric coating material is pH-sensitive and dissolves at pH above about 6.4.

12. The pharmaceutical composition of claim 1, wherein the enteric coating material is pH-sensitive and dissolves in normal human jejunum juice.

13. The pharmaceutical composition of claim 1, wherein the enteric coating material is pH-sensitive and the pharmaceutical composition substantially disintegrates in an aqueous medium at or above pH 5.5 within 1 hour.

14. The pharmaceutical composition of claim 1, wherein the enteric coating material is pH-sensitive and the pharmaceutical composition substantially disintegrates in an aqueous medium at or above pH 5.5 within 30 minutes.

15. The pharmaceutical composition of claim 1, wherein the coating material comprises an agent selected from the group consisting of cellulose phthalates, EUDRAGIT polymers, polyvinylacetate phthalate, SHELLAC, and cellulose acetate phthalate.

16. The pharmaceutical composition of claim 1, wherein the enteric coating material comprises EUDRAGIT L100.

17. The pharmaceutical composition of claim 1, wherein the enteric coating material comprises EUDRAGIT L100-55.

18. The pharmaceutical composition of claim 1, wherein the enteric coating material further comprises triacetin and TWEEN 80.

19. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition does not substantially disintegrate in an acidic, aqueous medium at pH 1.0-3.0 for at least 1 hour.

20. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition does not substantially disintegrate in an acidic, aqueous medium at pH 1.2-1.5 for at least 2 hours.

21. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition disintegrates substantially in an aqueous medium at pH 5.2-7.5 within 30 minutes.

22. The pharmaceutical composition of claim 1, wherein the amount of the enteric-coating material is 1-8% w/w in the composition.

23. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is in a form of tablet.

24. The pharmaceutical composition of claim 23, wherein the hardness of the tablet without the enteric-coat is at least 5 kp.

25. The pharmaceutical composition of claim 1, wherein the concentration of the drug is 0.1-10% w/w in the composition.

26. The pharmaceutical composition of claim 1, wherein the drug is contained in a drug core that is enteric-coated with the coating material.

27. The pharmaceutical composition of claim 26, further comprising:

a seal-coating material that coats the surface of the drug core and seals the drug from the moisture.

28. The pharmaceutical composition of claim 27, where the seal-coating material comprises hydroxy propylmethylcellulose.

29. The pharmaceutical composition of claim 27, where the seal-coating material comprises hydroxy propylmethylcellulose, TWEEN 80 and triacetin.

30. The pharmaceutical composition of claim 1, further comprising:

buffer salt in an amount sufficient to maintain the pH of the local environment to be 5.2-7.0 when the pharmaceutical composition is dissolved in the GI tract.

31. The pharmaceutical composition of claim 30, wherein the buffer salt is sodium or potassium phosphate.

32. The pharmaceutical composition of claim 1, further comprising:

one or more pharmaceutically acceptable excipient selected from the group consisting of diluent, lubricant, disintegrant, glidant or retention-enhancing excipient.

33. The pharmaceutical composition of claim 32, wherein the one or more excipient is blended with drug and the mixture of which forms a drug core.

34. The pharmaceutical composition of claim 33, wherein the drug core is directly coated with the enteric coat.

35. The pharmaceutical composition of claim 33, wherein the drug core is first sealed with a seal-coating material and then coated with the enteric coat.

36. The pharmaceutical composition of claim 32, wherein the diluent is selected from the group consisting of microcrystalline cellulose, lactose monohydrate, starch, gelatin, gum, tragacanth, calcium phosphate, sucrose, mannitol, sorbitol, and dextrose.

37. The pharmaceutical composition of claim 32, wherein the lubricant is selected from the group consisting of magnesium stearate, stearic acid, and calcium stearate.

38. The pharmaceutical composition of claim 32, wherein the disintegrant is selected from the group consisting of croscarmellose sodium, polyvinylpyrrolidone, polyvinylpolypyrrolidone, agar, alginic acid, a salt of alginic acid, sodium alginate, sodium starch glycolate, and starch.

39. The pharmaceutical composition of claim 32, wherein the disintegrant is selected from the group consisting of colloidal silica, talc, cornstarch, and syloid.

40. The pharmaceutical composition of claim 32, wherein the retention-enhancing excipient is selected from the group consisting of bioadhesive polymers, mucoadhesive polymers, swelling hydrogels, and viscogenic agents.

41. The pharmaceutical composition of claim 32, wherein the retention-enhancing excipient is selected from the group consisting of carboxyvinyl polymer, methyl cellulose, hydroxypropyl methylcellulose, and polycarbophil.

42. The pharmaceutical composition of claim 32, wherein the one or more excipient is a combination of microcrystalline cellulose, starch, colloidal silica and stearic acid.

43. The pharmaceutical composition of claim 42, wherein the drug and the one or more excipient are blended together to form a drug core which is then enteric-coated with the enteric coating material.

44. A method for treating a patient having a disease associated with abnormal cell proliferation, comprising:

orally administering to the patient a pharmaceutical composition comprising a water-soluble, acid-labile drug enteric-coated with an enteric coating material that dissolves at pH above about 5.2.

45. The method of claim 44, wherein the disease associated with abnormal cell proliferation is selected from the group consisting of hematological disorders, benign tumors, cancer, restenosis, and inflammatory diseases.

46. A method for treating a patient having an autoimmune disease, comprising:

orally administering to the patient a pharmaceutical composition comprising a water-soluble, acid-labile 2'-deoxyadenosine analog enteric-coated with a coating material that dissolves at pH above about 5.2.

47. The method of claim 46, wherein the autoimmune disease is selected from the group consisting of Sjogren's disease, systemic lupus erythematodes, glomerulonephritis, rheumatoid arthritis, generalized necrotizing angitis, granulomatous angitis, autoimmune thyroiditis, diabetes mellitus, myasthenia gravis, and multiple sclerosis.

48. The method of claim 46, wherein the 2'-deoxyadenosine analog is pentostatin.

49. A pharmaceutical composition, comprising: a camptothecin compound enteric-coated with an enteric coating material that dissolves at pH above about 5.2.

50. The pharmaceutical composition of claim 49, wherein the enteric coating material is pH-sensitive and dissolves at pH above about 5.8.

51. The pharmaceutical composition of claim 49, wherein the enteric coating material is pH-sensitive and dissolves at pH above about 6.4.

52. The pharmaceutical composition of claim 49, wherein the enteric coating material is pH-sensitive and dissolves in normal human jejeunum juice.

53. The pharmaceutical composition of claim 49, wherein the enteric coating material is pH-sensitive and dissolves at pH above about 5.8.

54. The pharmaceutical composition of claim 49, wherein the enteric coating material is selected from the group consisting of cellulose phthalates, EUDRAGIT polymers, polyvinylacetate phthalate, SHELLAC, and cellulose acetate phthalate.

55. The pharmaceutical composition of claim 49, wherein the enteric coating material is EUDRAGIT L100.

56. The pharmaceutical composition of claim 49, wherein the enteric coating material is EUDRAGIT L100-55.

57. The pharmaceutical composition of claim 49, wherein the enteric coating material further comprises triacetin and TWEEN 80.

58. The pharmaceutical composition of claim 49, wherein the camptothecin compound is selected from the group consisting of 9-nitro-20(S)-camptothecin, 9-amino-20(S)-camptothecin, 9-methyl-camptothecin, 9-chloro-camptothecin, 9-flouro-camptothecin, 7-ethyl camptothecin, 10-methyl-camptothecin, 10-chloro--camptothecin, 10-bromo-

camptothecin, 10-fluoro-camptothecin, 9-methoxy-camptothecin, 11-fluoro-camptothecin, 7-ethyl-10-hydroxy camptothecin, 10,11-methylenedioxy camptothecin, and 10,11-ethylenedioxy camptothecin, and 7-(4-methylpiperazinomethylene)-10,11-methylenedioxy camptothecin.

59. The pharmaceutical composition of claim 49, wherein the camptothecin compound is water-insoluble.

60. The pharmaceutical composition of claim 49, wherein the camptothecin compound is 9-nitro-20(S)-camptothecin.

61. The pharmaceutical composition of claim 49, further comprising one or more pharmaceutically acceptable excipient selected from the group consisting of diluent, lubricant, disintegrant, glidant or retention-enhancing excipient.

62. The pharmaceutical composition of claim 61, wherein the one or more excipient is blended with the drug and the mixture of which forms a drug core.

63. The pharmaceutical composition of claim 62, wherein the camptothecin compound is water-insoluble and the drug core is directly enteric coated with the enteric coating material.

64. The pharmaceutical composition of claim 62, wherein the camptothecin compound is water-soluble, and the drug core is first sealed with a seal-coating material and then coated with the enteric coat.

65. The pharmaceutical composition of claim 61, wherein the diluent is selected from a group consisiting of microcrystalline cellulose, lactose monohydrate, starch, gelatin, gum, tragacanth, calcium phosphate, sucrose, mannitol, sorbitol, and dextrose.

66. The pharmaceutical composition of claim 61, wherein the lubricant is selected from the group consisting of magnesium stearate, stearic acid, and calcium stearate.

67. The pharmaceutical composition of claim 61, wherein the disintegrant is selected from the group consisting of croscarmellose sodium, polyvinylpyrrolidone, polyvinylpolypyrrolidone, agar, alginic acid, a salt of alginic acid, sodium alginate, sodium starch glycolate, and starch.

68. The pharmaceutical composition of claim 50, wherein the disintegrant is selected from the group consisting of colloidal silica, talc, cornstarch, and syloid.

69. The pharmaceutical composition of claim 50, wherein the retention-enhancing excipient is selected from the group consisting of bioadhesive polymers, mucoadhesive polymers, swelling hydrogels, and viscogenic agents.

70. The pharmaceutical composition of claim 51, wherein the retention-enhancing excipient is selected from the group consisting of carboxyvinyl polymer, methyl cellulose, hydroxypropyl methylcellulose, and polycarbophil.

71. A method for treating a patient having a disease associated with abnormal cell proliferation, comprising:

orally administering to the patient a pharmaceutical composition comprising a camptothecin compound enteric-coated with a enteric coating material that dissolves at pH above about 5.2.

72. The method of claim 50, wherein the disease associated with abnormal cell proliferation is selected from the group consisting of hematological disorders, benign tumors, cancer, restenosis, and inflammatory diseases.